

**REMARKS**

In furtherance of the their previous response and arguments and the Examiner's Interview conducted September 29, 2003, the applicants offer the following argument and the enclosed Rule 132 Declaration of inventor Therese-Marie Jourdiier.

During the Examiner's interview, the Examiner acknowledged that the results in the table on page 19 were surprising, but alleged that they were limited to the inguinal and iliac lymph nodes. In the enclosed Rule 132 Declaration, Dr. Jourdiier attests that the results displayed in this table are not limited to the inguinal and iliac lymph nodes, but that one of ordinary skill in the art would understand that a similar immune response would be present in other lymph nodes of the rectogenitourinary system owing to the highly complex and integrated nature of the rectogenitourinary lymph node system.

Dr. Jourdiier also attests that the data on page 20 of the specification demonstrate that the immune response following injection to the thigh was targeted to the rectogenitourinary mucous membranes as well.

In view of the foregoing, therefore, the applicants respectfully submit that the present claims cannot be obvious.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Date: October 29, 2003

Respectfully submitted,

  
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Serial No. 09/720,513  
Attorney Docket No. 00-1282

October 29, 2003

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
(Case No. 00-1282)

In the Application of:	)	
	)	
Jourdier et al.	)	Examiner: Bao Q. Li
	)	
Serial No.: 09/720,513	)	Group Art Unit: 1648
	)	
Filing Date: March 26, 2001	)	Confirmation No.: 1648
	)	
For: Mucosal Targeting Immunisation	)	

**DECLARATION OF THERESE-MARIE JOURDIER UNDER 37 C.F.R. § 1.132**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Therese-Marie Jourdier, declare as follows:

1. I am a named inventor of the above-captioned patent application.
2. I have a doctorate in Microbiology, specializing in virology. My doctoral thesis was entitled, "Establishment of experimental animal models for the study of the infection by the virus Herpes simplex."
3. I am currently the Head of the Animal Experimentation Unit in the Research / Microbiology Department of Aventis Pasteur S.A. I have been employed by Aventis Pasteur S.A. and its predecessor companies since 1975, when I began working in the microbiology department. Since 1983 my work has centered on the establishment of animal models to access inoculation parameters and immunogenicity of antigens under consideration by our company.
4. Based on my education and 20 years of experience referred to above, I am considered an expert in animal experimentation, being authorized by the French Agriculture and Fishing Ministry (sub-direction of Health and Animal Protection) to undertake and supervise experimentation on a large panel of live vertebrate animals.

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5. On information and belief I understand that the U.S. patent examiner has acknowledged that the results presented in the specification of the immune response in the iliac and inguinal lymph nodes following inoculation in the thigh are unexpected. I further understand, however, that the examiner has opined that the data are limited to the iliac and inguinal lymph nodes and are not indicative of an immune response in other rectogenitourinary lymph nodes or mucous membranes.
6. The data in the tables on page 19 and 20 of the specification are the immune response results following intramuscular injection to the thigh of rhesus macaques of vCP205 (a construct of an attenuated canarypox virus (ALVAC) capable of expressing the env, gag, and pro genes of the HIV-1 virus) followed by adjuvanted gp160 MN/LAI.
7. As the data in the table on page 19 display, the number of anti-gp160 IgG B lymphocytes per  $10^6$  mononucleated cells observed in the internal and external iliac lymph nodes and the inguinal lymph nodes ranged from about 18 to about 350 times more than in the submaxillary and axillary lymph nodes and in the blood.
8. As the data on page 20 of the specification display, which reports on the ratio of the specific anti-gp160 IgG activity at the time of animal sacrifice compared to just before late booster with the adjuvanted gp160 MN/LAI, significantly positive secretion of IgG was observed in rectal and vaginal washes as well as in urine, indicating immune responses in the corresponding rectogenitourinary mucous membranes.
9. These data demonstrate that the immune response was targeted to the rectogenitourinary lymph node system and mucous membranes. Furthermore, because the rectogenitourinary lymph node system is highly complex and integrated, one of ordinary skill in the art would understand that an immune response similar to that observed in internal and external iliac lymph nodes and inguinal lymph nodes would be present in other lymph nodes of the rectogenitourinary system.
10. I further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like

so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Thérèse-Marie JOURDIER  
Therese-Marie Jourdier

Date: 21<sup>st</sup> October 2003

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